



September 25, 2026

Ezisurg Medical Co., Ltd.
% Giselle Zhang
Lead RA&QA Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Rd.
Bldg. 1, Suite 300
Austin, Texas 78746

Re: K254291

Trade/Device Name: easyEndo™ E-Lite Single Use Powered Endoscopic Staplers
easyEndo™ E-Lite Single Use Powered Endoscopic Staplers with Curved Tip
easyEndo™ E-Lite Single Use Cartridges

Regulation Number: 21 CFR 878.4750

Regulation Name: Implantable Staple

Regulatory Class: Class II

Product Code: GDW, GAG

Dated: August 25, 2026

Received: August 25, 2026

Dear Giselle Zhang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.

Assistant Director

DHT4B: Division of Plastic and

Reconstructive Surgery Devices

OHT4: Office of Surgical and

Infection Control Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K254291

Device Name

easyEndo™ E-Lite Single Use Powered Endoscopic Staplers

easyEndo™ E-Lite Single Use Powered Endoscopic Staplers with Curved Tip

easyEndo™ E-Lite Single Use Cartridges

Indications for Use (Describe)

easyEndo™ E-Lite Single Use Powered Endoscopic Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general and thoracic surgical procedures.

easyEndo™ E-Lite Single Use Powered Endoscopic Staplers with Curved Tip are intended for transection, resection, and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general and thoracic surgical procedures.

easyEndo™ E-Lite Single Use Cartridges are intended for transection, resection, and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general and thoracic surgical procedures.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

(K254291)

easyEndo™ E-Lite Single Use Powered Endoscopic Staplers and Cartridges

1. Submission Sponsor

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3. Date Prepared

09/23/2026

4. Device Identification

Trade/Proprietary Name:	easyEndo™ E-Lite Single Use Powered Endoscopic Staplers easyEndo™ E-Lite Single Use Powered Endoscopic Staplers with Curved Tip easyEndo™ E-Lite Single Use Cartridges
Classification Name:	Staple, Implantable
Regulation Number(s):	21 CFR 878.4750
Product Code(s):	GDW
Class:	II
Classification Panel:	General & Plastic Surgery
Classification Name:	Stapler, Surgical

Regulation Number(s): 21 CFR 878.4800
Product Code(s): GAG
Class: II
Classification Panel: General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

Device name: ECHELON, ECHELON ENDOPATH™ and ECHELON FLEX families of endoscopic linear cutters and reloads
510(k) number: K202665
Manufacturer: Ethicon Endo-Surgery, LLC

Device Name: Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip
510(k) Number: K141952
Manufacturer: Ethicon Endo-Surgery, LLC

6. Device Description

The easyEndo™ E-Lite (previously named: easyEndo™ Powered) Single Use Powered Endoscopic Staplers and Cartridges, hereafter E-Lite Staplers and Cartridges, are sterile, single patient use instruments that simultaneously cut and staple tissue through a battery powered firing system. The E-Lite Staplers and Cartridges are sterilized by irradiation. The instruments deliver six staggered rows of staples, three on either side of the cut line.

The staplers are available in three shaft lengths of 260mm, 350mm and 440mm. The Articulation Knob can articulate the jaws to 60 degrees, 45 degrees, 30 degrees, and 15 degrees in each set direction to facilitate lateral access to the operative site.

The device has two staple line lengths, 45 mm and 60 mm. The staplers are packaged with a primary lithium battery pack that must be installed prior to use. The staplers are packaged without a cartridge and must be loaded prior to use.

The lock out feature is designed to prevent a used or improperly installed Cartridge from being re-fired or the Stapler from being fired without a Cartridge.

7. Indication for Use Statement

easyEndo™ E-Lite Single Use Powered Endoscopic Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general and thoracic surgical procedures.

easyEndo™ E-Lite Single Use Powered Endoscopic Staplers with Curved Tip are intended for transection, resection, and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general and thoracic surgical procedures.

easyEndo™ E-Lite Single Use Cartridges are intended for transection, resection, and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general and thoracic surgical procedures.

8. Substantial Equivalence Discussion

The following table compares the easyEndo™ to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device shares the same intended use with the predicates for transection, resection, and/or creation of anastomoses, but the safety and effectiveness of this device have not been studied for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen. Although the subject device has more limited indications for use and differs in some technological characteristics, safety and performance data demonstrates that these differences do not raise any new questions of safety or effectiveness compared to the predicate device

Table 1 - Comparison of Stapler Characteristics

Item	easyEndo™ E-Lite Single Use Powered Endoscopic Staplers (Proposed device)	ECHELON, ECHELON ENDOPATH™ and ECHELON FLEX families of endoscopic linear cutters and reloads (Primary Predicate: K202665)	Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip (Secondary Predicate: K141952)	SE Discussion
Manufacturer	Ezisurg Medical Co., Ltd.	Ethicon Endo-Surgery, LLC	Ethicon Endo-Surgery, LLC	/
Product Code	GDW	GDW	GDW	Same
Classification	Class II (21 CFR 878.4750 & 21 CFR 878.4740)	Class II (21 CFR 878.4750)	Class II (21 CFR 878.4750)	Same
Indications for Use	easyEndo™ E-Lite Single Use Powered Endoscopic Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general and thoracic surgical procedures.	ECHELON, ECHELON ENDOPATH™ and ECHELON FLEX families of endoscopic linear cutters and reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric	The Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip and it's reloads are intended for transection and resection of tissue and vasculature. The instruments have application in multiple open or minimally invasive general gynecologic, urologic,	The subject device has a more limited indication for use than the predicate device which is acceptable.

		surgical procedures. They can be used with staple line or tissue buttressing materials. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.	thoracic, and pediatric surgical procedures.	
Operating Principle	Powered	Powered	Powered	Same
Cutting Mechanism	Stapler places two, triple staggered rows of staples and simultaneously cuts and divides the tissue between the two rows.	Stapler places two, triple staggered rows of staples and simultaneously cuts and divides the tissue between the two rows.	Four staggered rows of staples, two on either side of the cut line.	Equivalent
Jaw Structure	Linear, Curved	Linear	Curved	Equivalent
Lock-out Feature	Yes	Yes	Yes	Same
Main Components	Cutting Knife Anvil Jaw (with or without Curved Tip) Staple Battery Pack Shaft	Cutting Knife Anvil Jaw Staple Battery Pack Shaft	Cutting Knife Anvil Jaw (with Advanced Placement Tip) Staple Battery Pack Shaft	Equivalent
Suture Length	45mm, 60mm	45mm, 60mm	35 mm	Equivalent
Articulation Degree	Total 120° (60° in each direction)	Total 90° (45° in each direction)	Total 100° (50° in each direction)	Equivalent
Sterilization	Irradiation sterilization	Irradiation sterilization	Irradiation sterilization	Same
Materials or substances contacted with patient	Anvil jaw: Stainless steel 05Cr17Ni4Cu4Nb, Stainless steel 06Cr19Ni10 (304)	Stainless steel	Stainless steel	Equivalent

	Stainless steel 12Cr17Ni7 Curved Tip: Stainless steel 05Cr17Ni4Cu4Nb and Stainless steel 12Cr17Ni7			
	Shaft: stainless steel 06Cr19Ni10	Stainless steel	Stainless steel	
	Cutting knife: stainless steel 20Cr13	Stainless steel	Stainless steel	

Table 2 - Comparison of Cartridge Characteristics

Item	easyEndo™ E-Lite Single Use Cartridges (Proposed device)	ECHELON, ECHELON ENDOPATH™ and ECHELON FLEX families of endoscopic linear cutters and reloads (Primary Predicate: K202665)	Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip and reloads (Secondary Predicate: K141952)	SE Discussion
Manufacturer	Ezisurg Medical Co., Ltd.	Ethicon Endo-Surgery, LLC	Ethicon Endo-Surgery, LLC	/
Product Code	GDW, GAG	GDW	GDW	Same
Classification	Class II (21 CFR 878.4750 & 21 CFR 878.4740)	Class II (21 CFR 878.4750)	Class II (21 CFR 878.4750)	Same
Indications for Use	easyEndo™ E-Lite Single Use Cartridges are intended for transection, resection, and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general and thoracic surgical procedures.	ECHELON, ECHELON ENDOPATH™ and ECHELON FLEX families of endoscopic linear cutters and reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical	The Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip and its reloads are intended for transection and resection of tissue and vasculature. The instruments have application in multiple open or minimally invasive general gynecologic, urologic,	The subject device has a more limited indication for use than the predicate device which is acceptable.

			procedures. They can be used with staple line or tissue buttressing materials. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.	thoracic, and pediatric surgical procedures.	
Staple height	Open staple height	2.0 mm, 2.5 mm, 3.5 mm, 3.8 mm, 4.1 mm, 4.4 mm	2.0 mm, 2.6 mm, 3.6 mm, 3.8 mm, 4.1 mm, 4.2 mm	2.5 mm	Equivalent
	Closed staple height	0.75 mm, 1.0 mm, 1.5 mm, 1.7 mm, 2.0 mm, 2.3 mm	0.75 mm, 1.0 mm, 1.5 mm, 1.8 mm, 2.0 mm, 2.3 mm	1.0mm	
Row Number of Staples		6	6	4	Equivalent
Staple Shape		Standard “B” shaped staple	Standard “B” shaped staple	Standard “B” shaped staple	Same
Materials or substances contacted with patient	Staples: Unalloyed Titanium (Ti Grade 2)		Staples: titanium (Ti3Al2.5V) alloy	Staples: titanium (Ti3Al2.5V) alloy	Equivalent
	Cartridge jaw: Stainless steel 05Cr17Ni4Cu4Nb,		Stainless steel	Stainless steel	
	Cartridge: PA		Unknown	Unknown	

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of easyEndo™ E-Lite Single Use Powered Endoscopic Staplers and Cartridges and to show substantial equivalence to the predicate device, Ezisurg completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The easyEndo™ E-Lite Single Use Powered Endoscopic Staplers and Cartridges passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Staple height and formation
- Staple line strength
- Staple line integrity

- Leak-burst pressure testing
- Clamping Force
- Obstruction and lockout testing
- Functional testing
- Electrical safety and EMC testing in accordance with IEC 60601-1 and IEC 60601-1-2 standards
- Biocompatibility of materials according to ISO 10993 standards
- Sterilization, packaging, transportation and shelf-life validations.

Additionally, Human Factors testing was executed in accordance with the FDA Guidance Document Applying Human Factors and Usability Engineering to Medical Devices.

10. Animal Study

Animal testing was conducted in alignment with good laboratory practices (GLP) per 21 CFR §58.

The study is intended to evaluate the safety effectiveness and handling characteristics of easyEndo™ E-Lite in a chronic and acute animal study with the predicate devices. Animals have been divided into test and control groups and performed transection, resection, and/or the creation of anastomoses on target tissues or vasculature, according to the corresponding indications and specific tissue types.

In terms of safety and performance, there was no significant difference between the test and control groups, and all evaluation indicators met the acceptance criteria.

11. Clinical Performance Data

No clinical data was necessary to determine the substantial equivalence of this device.

12. Statement of Substantial Equivalence

The easyEndo™ E-Lite Single Use Powered Endoscopic Staplers and Cartridges have the same intended use as the predicate devices and similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated the easyEndo™ E-Lite Single Use Powered Endoscopic Staplers and Cartridges is as safe and effective as the predicate device. Therefore, the easyEndo™ E-Lite Single Use Powered Endoscopic Staplers and Cartridges is substantially equivalent to the predicate device.